

20. The method of claim 13, wherein the interleukin-11 is administered daily until improvement of necrotic injury is observed.--

#### **REMARKS**

This amendment is filed along with a request for continued examination of for the above-referenced patent application. Upon entry of the present amendment, claims 1-20 will be pending in the application. Claims 1, 3, and 6 have been amended and new claims 10-20 added. Support for the amendments to claims 1, 3, and 6 appears in the specification at, e.g., the paragraph bridging pages 8 and 9 (disclosing the administration of IL-11 to a mammal at risk for developing complement-mediated cytotoxicity). Support for new claims 10-20 appears in the specification at, e.g., the paragraph bridging pages 11 and 12 (disclosing human treatment of human subjects) and at page 3, first and second paragraph, and in the specification at page 9, second paragraph (disclosing the use of IL-11 in treating necrotic injury). No new matter has been added by these amendments. An Appendix showing the amendments to the claims is attached.

The Examiner objected to the declarations as not including a reference to the previous provisional patent application. Applicants note that declarations with a reference to the priority document were submitted along with the request for the continued prosecution application dated May 10, 2001. Accordingly, it is believed this objection is moot.

Applicants will submit formal drawings upon indication of allowable subject matter. The specification has been amended to include reference to the provisional patent application.

# Rejections under 35 USC 112, second paragraph

Claim 4 is rejected as indefinite for reciting an ng quantity. Applicants traverse the rejection. The term "ng" is recognized by one of ordinary skill in the art as an abbreviation for nanograms. Accordingly, the metes and bounds of claim 4 are not rendered indefinite by recitation of this term. Reconsideration and withdrawal of the rejection is requested.

## Rejection under 35 USC 102(a)

Claim 1 is rejected as anticipated by Hill et al., J. Clin. Invest. 102:115-23, 1998 ("Hill"). The rejection is traversed to the extent is applied to the claims as amended.

Claim 1 has been amended to specify identifying a mammal at risk of developing complement-mediated cytotoxicity and then administering interleukin-11 (IL-11) to a subject in need of such treatment. Hill is generally silent about the relationship between complement-mediated cytotoxicity and administration of IL-11. More particularly, the reference fails to disclose or suggest the step of identifying a mammal at risk for developing complement-mediated cytotoxicity, which is required by the claim. Accordingly, Hill fails to describe the invention now claimed. Reconsideration and withdrawal of the rejection is requested.

## Rejection under 35 USC 102(b)

Claim 6 is rejected as anticipated by Yang et al., US Patent No. 5,700,664 ("Yang").

Claim 6 has been amended to specify that the recited method requires identifying a mammal at risk of developing complement-mediated cytotoxicity and then administering interleukin-11 (IL-11) to a subject in need of such treatment. Yang is silent about the relationship between complement-mediated cytotoxicity and administration of IL-11, and does not teach or suggest

that Il-11 can be administered to treat this cytotoxicity. More particularly, the reference fails to disclose the identifying step required by the claims. Accordingly, Yang fails to describe the invention now claimed. Reconsideration and withdrawal of the rejection is requested.

### Rejection under 35 USC 103(a)

Claims 1-9 are rejected as obvious over Hill in view of Yang. The rejection is traversed to the extent it is applied to the claims as amended.

As discussed above, claim 1 (from which depends claim 2) has been amended to specify that the recited method specifies identifying a mammal at risk of developing complement-mediated cytotoxicity and then administering interleukin-11 (IL-11) to a subject in need of such treatment. Claim 3 (from which depends claims 4 and 5) and claim 6 (from which depends claims 7-9) have similarly been amended to recite identifying a mammal at risk of developing complement-mediated cytotoxicity and then administering IL-11. The references in combination do not suggest the invention now claimed.

Hill and Yang have been discussed above. Neither reference suggests that IL-11 can be administered to a mammal at risk for developing complement-mediated cytotoxicity.

Accordingly, the combination of references fails to render obvious the invention now claimed. Reconsideration and withdrawal of the rejection is requested.

#### **CONCLUSION**

Applicants submit that the application is in condition for allowance and such action is respectfully requested. Should any questions or issues arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

A petition for extension of time accompanies this response, as does a check for payment of one excess independent claim. The Commissioner is hereby authorized to charge payment of any additional fees required in connection with the papers transmitted herewith, or credit any overpayment of same, to Deposit Account No. 50-0311 (Reference No. 22058-521).

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Respectfully submitted,

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#### **Appendix**

1. (Amended) A method of preventing [an immune-mediated disorder] <u>complement-mediated cytotoxicity in a mammal</u> which comprises

identifying a mammal at risk of developing complement-mediated cytotoxicity; and administering to [a] said mammal, prior to tissue transplantation, a therapeutically effective amount of interleukin-11, wherein said amount of IL-11 prevents complement-mediated cytotoxicity in said mammal.

3. (Amended) A method of ameliorating [an immune-mediated disorder] <u>complement-mediated cytotoxicity in a mammal</u> which comprises

identifying a mammal at risk of developing complement-mediated cytotoxicity; and administering, at the time of tissue transplantation, a therapeutically effective amount of interleukin-11, wherein said amount of IL-11 prevents complement-mediated cytotoxicity in said mammal.

6. (Amended) A method of treating [an immune-mediated disorder] complement-mediated cytotoxicity in a mammal which comprises

identifying a mammal with complement-mediated cytotoxicity and administering to [a] said mammal [experiencing said immune-mediated disorder] a therapeutically effective amount of interleukin-11, wherein said amount of IL-11 prevents complement-mediated cytotoxicity in said mammal.